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| 10/790,173 | 03/01/2004 | Fred H. Burbank | R0367-00103 | 1003 |
| 61808 | 7590 | 08/20/2008 | | |
| EDWARD J. LYNCH, PATENT ATTORNEY | | | EXAMINER | |
| ONE EMBARCADERO CENTER | | | TOWA, RENE T | |
| SUITE 562 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| <i>Office Action Summary</i> | Application No. | Applicant(s) |
|-------------------------------------|------------------------------|-------------------------|
| | 10/790,173 | BURBANK ET AL. |
| | Examiner RENE TOWA | Art Unit 3736 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 May 2008.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,40-45 and 47-53 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,40-45 and 47-53 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/20/08.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ .
5) Notice of Informal Patent Application (PTO-152)
6) Other: ____ .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 23, 2008 has been entered.
2. This Office action is responsive to the amendments filed May 23, 2008. Claims 1, 40-45 and 47-53 are pending. No new claim has been added. Claim 1 has been amended. Claims 2-39, 46 and 54-56 have been cancelled.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. **Claims 1, 40-43, and 47-53** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis (US 5,794,626) in view of Tihon et al. (US 5,415,656), and further in view of Burbank et al. (US 5,526,822).

- ***Regarding claims 1, 40-43 & 47-53 (general content of the prior art):***

In regards to **claim 1**, Kieturakis discloses a biopsy instrument 5 for retrieving tissue specimen from surrounding tissue at a target site, having a longitudinal axis and tissue penetrating distal tip 45, comprising:
a housing;

an elongated shaft 40 having a longitudinal axis and a proximal end within the housing (see figs. 3-4); and

an elongated cutting element 15 disposed on a distal portion of the instrument, which is actuatable between a radially retracted position and a radially extended position and which is rotationally movable in said radially extended position to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see abstract; see figs. 3 & 5-8);

an outer sheath (not shown) slidably disposed about the shaft and configured for axial movement between distal and proximal positions for selectively covering and uncovering the cutting element (see column 9/lines 11-17);

a rotating driving member in the housing connected to the proximal portion of the elongated shaft 40 to rotate the shaft 40 with respect to the housing and to rotate the elongated cutting element 15 secured to the distal portion of the shaft 40 (see column 6/lines 44-62); and

a longitudinal driving member 30 (see column 4/line 59 to column 5/line 2) slidably disposed within the outer sheath having a proximal portion in the housing and a distal portion connected to the elongated electrosurgical cutting element to actuate the cutting element between the radially retracted position and the radially extended position (see figs. 1-3; col. 3, lines 61-67; col. 6, lines 13-19; col. 9, lines 11-17).

In regards to **claim 42**, Kieturakis discloses a biopsy instrument wherein the cutting element 15 has a proximal end 23 and a distal end 24 and which is configured to

move one end closer to the other end to effect radial extension from the retracted position to the radial extended position (see fig. 2).

In regards to **claim 43**, Kieturakis discloses a biopsy instrument wherein the cutting element 15 is configured so that the distal end 24 is fixed and the proximal end 23 moves toward the distal end 24 in order to radial extend the cutting element 15 (see figs. 2-3).

In regards to **claim 47**, Kieturakis discloses a biopsy instrument including a proximal driver unit 150 for controlling radial expansion and retraction of the cutting element and rotation of the cutting element about the longitudinal axis (see col. 6, lines 13-19, 44-52, 56-62 & 66-67; col. 7, lines 1-4 & 31-36; col. 8, lines 2-10).

In regards to **claim 49**, Kieturakis discloses a biopsy instrument wherein the cutting element 15 is configured to be manipulated to segment the tissue specimen (see figs. 2-3; col. 3, lines 61-67).

In regards to **claim 50**, Kieturakis discloses a biopsy instrument wherein the electrosurgical proximal tissue cutting element 15 is configured to segment the tissue specimen after it has been isolated from the surrounding tissue (see figs. 2-3; col. 3, lines 61-67).

In regards to **claim 51**, Kieturakis discloses a biopsy instrument wherein the tissue cutting element 15 is capable of segmenting the tissue specimen as it is being retracted from said radially extended position to said radially retracted position (see figs. 2-3).

In regards to **claim 52**, Kieturakis discloses a biopsy instrument wherein the radially extended position comprises a first radially extended position, and wherein the cutting element 15 is further actuatable to a plurality of additional radially extended positions and rotatable about the longitudinal axis in each of said radially extended positions to selectively peripherally segment said tissue specimen (see figs. 2-3).

In regards to **claim 53**, Kieturakis discloses a biopsy instrument wherein the instrument further comprises a cannula 10 having a lumen 56 for providing a passageway into the patient's body; the segments of the tissue specimen being removable from the patient's body through the cannula 10 (see fig. 3).

Kieturakis discloses an instrument, as described above, that fails to expressly teach an electrosurgical cutting element, an automatically controllably sliding outer sheath, a first driving member to move the outer sheath, or a second driving member to axially move the elongated shaft.

However, **Tihon et al.** disclose an apparatus comprising an electrosurgical cutting wire 1, energized by radio frequency (RF) energy; wherein an electrical conductor 35 having a distal end electrically connected to the electrosurgical cutting element and a proximal end configured to be connected to a source ESU to deliver radio frequency energy from the source to the electrosurgical cutting element (see figs. 2 & 8; col. 1, lines 65-68; col. 2, lines 1-5 & 20-31; col. 3, lines 21-33; col. 5, lines 56-64; col. 8, lines 32-41).

Moreover, **Burbank et al.** disclose a biopsy instrument for retrieving tissue specimen from surrounding tissue at a target site; wherein the instrument includes a first

longitudinal driving member 64 in the housing secured to an outer sheath 268 is configured to axially move the outer sheath 268 between distal and proximal positions (see fig. 11A; col. 17, lines 31-37); wherein a second longitudinal driving member 64 in the housing 14 secured to the proximal portion of an elongated shaft 44 configured to axially move the elongated shaft 44 (see figs. 1K, 2 & 4; col. 13, lines 18-19; col. 14, lines 2-8, 18-22 & 26-43; col. 16, lines 49-67; col. 17, lines 1-9).

Applying the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) and are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

- ***In regards to claims 1 & 40-41 (motivation to combine):***

Since both Kieturakis and Tihon et al. teach radially retractable cutting elements associated with medical devices for cutting tissue, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Kieturakis with an electrosurgical cutting element as taught by Tihon et al. in order to make the cutting operation easier, more direct and thus less traumatic, than cutting with an unpowered cutter. Moreover, use of RF powered cutting element permits the convenient application of coagulating power for hemostasis (see Tihon et al., column 1/line 65 to column 2/line 5).

Both Kieturakis and Burbank et al. teach biopsy devices associated with a stereotactic apparatus for axially directing a needle tip into a lesion in the patient (see abstract, figure 10 & col. 6, lines 13-17; col. 7, lines 15-18 & 47-50; col. 8, lines 2-5 of Kieturakis; see figs. 1K, 2 & 4; col. 13, lines 18-19; col. 14, lines 2-8, 18-22 & 26-39; col. 16, lines 49-67; col. 17, lines 1-9 of Douglas et al.); since Douglas et al. also teach a second longitudinal driving member 64 mounted on the housing 14 for axially moving the elongated shaft 44 in order to fine tune the location of the tissue penetrating distal tip 45 of the shaft 44 (see col. 14, lines 2-8, 18-22 & 26-39), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the apparatus of Kieturakis as modified by Tihon et al. above with a second longitudinal driver as taught by Burbank et al. in order to fine tune the location of the tissue penetrating distal tip of the shaft.

Moreover, since Kieturakis teaches an automated biopsy apparatus that includes an outer sheath that is slidably disposed about the shaft such that the outer sheath is configured to axially move between distal and proximal positions for selectively covering and uncovering the cutting element (see col. 9, lines 11-17), and Burbank et al. teach a mechanism for axially moving an outer sheath between distal and proximal locations (see fig. 11A; col. 17, lines 31-37), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the apparatus of Kieturakis as modified by Tihon et al. above with a driving member for axially moving the outer sheath as taught by Burbank et al. in order to automatically selectively cover and uncover the cutting element. Moreover, it has previously been held that merely making

automatic is not patentable--See *In re Venner*, 262 F.2d 91, 95, 120 USPQ 192, 194 (CCPA 1958).

- ***In regards to claim 48 (motivation to combine):***

Kieturakis discloses a biopsy instrument wherein the proximal driver unit 150 further controls axial movement of said shaft 40 (see col. 6, lines 13-19, 44-52, 56-62 & 66-67; col. 7, lines 1-4 & 31-36; col. 9, lines 11-17); since Kieturakis teaches an automated biopsy apparatus that includes an integrated proximal driver unit 150 to automatically actuate the various actuation mechanisms of the biopsy apparatus in preprogrammed cycles (see col. 7, lines 31-37), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the apparatus of Kieturakis as modified by Tihon et al. and Burbank et al. above with a proximal driver unit that controls axial movement of the shaft and sheath in order to permit the controller to automatically actuate the various actuation mechanisms in preprogrammed cycles including axial shaft movement and covering/uncovering of the cutting element.

5. **Claims 44-45** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis ('626) in view of Tihon et al. ('656), Burbank et al. ('822), and further in view of Treat (US 4,493,320).

Kieturakis as modified by Tihon et al. and Burbank et al. discloses a system, as described above, that teaches all the limitations of claims 44-45 except for a bipolar or monopolar electrode.

However, **Treat** discloses a system comprising a bipolar electrode 24 (see fig. 3; column 3/lines 14-19; column 4/lines 44-49).

Because Kieturakis discloses a device for rotatably cutting a volume of tissue using radially retractable cutting elements; Tihon et al. teach that it is beneficial to cut tissue using an electrosurgical radially retractable electrode cutting element; and, Treat teaches advantages provided by a bipolar electrode cutting element, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the instrument of Kieturakis as modified by Tihon et al. and Burbank et al. with a bipolar electrode cutting element as taught by Treat in order to localize the cauterization to a small predefined volume of tissue (see Treat, column 2/lines 31-41).

Similarly, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Kieturakis as modified by Tihon et al. and Burbank et al. with a monopolar electrode as claimed in order to cauterize an undefined volume of tissue.

Response to Arguments

6. Applicant's arguments filed May 23, 2008 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/R. T./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736